R E M A R K S

Claims 19, 20, 23, 24, 29-31, 33, 34, 36, 38 and 40-43 are pending and stand ready for further action on the merits. Claims 19, 23, 24, 29-31, 33, 34 and 40 have been withdrawn from consideration as being drawn to non-elected subject matter.

Independent claims 19, 20 and 42 have been amended to recite the subject matter of the disclosure at page 12, lines 13-15. Also, new claims 44-48 find support on page 12, lines 13-15.

No new matter has been added by way of the above amendment.

Restriction

The Examiner has newly imposed a restriction requirement as between:

Group I - Process claims 19, 23, 24, 29-31, 33, 34 and 40; and

Group II - product claims 20, 36, 38 and 41-43.

The Examiner indicates that the process claims of Group I have been withdrawn from consideration as being drawn to non-elected subject matter by original presentation. However, the Examiner has not provided any reason as to why the process claims are restrictable from the inventive product claims.

Accordingly, Applicants respectfully request rejoinder of Group I with Group II.

However, should the Examiner maintain the restriction requirement, Applicants respectfully remind the Examiner that

should the product claims be found allowable, the process claims which depend from or otherwise include all the limitations of the allowable product claims are to be rejoined, see MPEP § 821.04.

Written Description Requirement

Claims 20, 36, 38 and 41-43 are rejected under 35 U.S.C. 112, first paragraph. The Examiner asserts that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse this rejection.

In response to this rejection, Applicants have amended the independent claims to recite that the IRES's originate from plant viruses having a plus-sense single-stranded RNA genome. Applicants respectfully submit that the inventive disclosure conveys with reasonable clarity to those skilled in the art, that, as of the filing date sought, the present inventors were in possession of the invention, and that the invention in that context, is what is now claimed. The presently claimed disclosure therefore satisfies the requirements set forth in *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

An applicant may show possession of the claimed invention in a variety of ways including description of an actual reduction to

practice, or by showing that the invention was "ready for patenting" such as by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); and *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court in *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) stated that all that is necessary to satisfy the written description requirement is to define the compound by "whatever characteristics sufficiently distinguish it".

In the present case, the description in the specification contains sufficient guidance for the skilled artisan to prepare the recombinant DNA molecule of claim 20 comprising IRES's that originate from plant viruses with plus-sense single-stranded RNA genome.

Plant viruses with plus-sense single-stranded RNA genome were generally known before the priority date of the application. Reference may be made to the following book: R. Matthers, (1992) "Fundamentals of Plant Virology", Elsevier; or to the following two review articles: Buck, K.W., (1996) "Comparison of replication of positive-stranded RNA viruses of plants and animals" Adv. Virus.

Res., 47, 159-251 and Goldbach, R. & Wellink, J. "Evolution of plus-strand RNA viruses" Intervirology, 29, 260-267.

The application also teaches the skilled artisan where to look for an IRES sequence in such viruses, namely upstream of the movement protein (MP) or the coat protein (CP) genes (see e.g. page 6, lines 19 to 22; page 6, lines 27 and 28; page 7, lines 17 to 19; page 8, etc.). These genes can be readily identified, since plant viruses with plus-sense single-stranded RNA genome contain only a small number of genes, typically below ten; CrTMW and TMW UQ1 contain three genes only, namely a gene coding for two components of a replicase, a movement protein gene, and a coat protein gene. Thus, Applicants believe that the claims limited to IRESs from plant viruses with plus-sense single-stranded RNA genome are sufficiently supported by the description of the application.

Finally, it should be pointed out to the Examiner that the present invention is a fundamental invention, i.e., it describes the first IRES sequences that are active in plants and plant cells. Limiting the scope of the claims to tobamoviral IRESs or even to the specific IRESs of the examples does not provide the inventors with an adequate protection relative to their contribution to the art.

Based on the foregoing, Applicants respectfully submit that the inventive disclosure provides sufficient description support for the claimed invention, which includes a cDNA sequence

element designated as an internal ribosome entry site (IRES), which is located 3' to the first plant-expressible gene and wherein said IRES is a eukaryotic, plant-specific IRES that originates from a plant virus having a plus-sense single-stranded RNA genome, as presently claimed. As such, withdrawal of the written description rejection under 35 U.S.C. 112, first paragraph, is respectfully requested.

Enablement

Claims 20, 36, 38 and 41-43 are rejected under 35 U.S.C. 112, first paragraph. The Examiner has taken the position that the specification, while enabling for an IRES of crTMV origin, does not reasonably provide enablement for any IRES of plant viral origin.

Applicants respectfully traverse the rejection.

MPEP §2164.01(a) sets forth that there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicants respectfully submit that in applying each of these above-factors to the claimed invention, as amended above, there is sufficient guidance for the skilled artisan to make and/or use the present invention. The Examiner will note that independent claims 19, 20 and 42 now recite that the IRES's originate from plant viruses having a plus-sense single-stranded RNA genome.

As mentioned above, plant viruses with plus-sense single-stranded RNA genome were generally known before the priority date of the application, e.g., R. Matthers, (1992) "Fundamentals of Plant Virology", Elsevier; Buck, K.W., (1996) "Comparison of replication of positive-stranded RNA viruses of plants and animals" Adv. Virus. Res., 47, 159-251; and Goldbach, R. & Wellink, J. "Evolution of plus-strand RNA viruses" Intervirology, 29, 260-267.

The skilled artisan is provided guidance in the specification as to where to look for an IRES sequence in such viruses, namely upstream of the movement protein (MP) or the coat protein (CP) genes (see e.g. page 6, lines 19 to 22; page 6, lines 27 and 28;

page 7, lines 17 to 19; page 8, etc.). These genes can be easily identified, since plant viruses with plus-sense single-stranded RNA genome contain only a small number of genes, typically below ten; CrTMW and TMW UQ1 contain three genes only, namely a gene coding for two components of a replicase, a movement protein gene, and a coat protein gene. Thus, Applicants believe that the skilled artisan could make and/or use the presently claimed invention limited to IRES's from plant viruses with plus-sense single-stranded RNA genome without undue experimentation.

MPEP § 2164.04 instructs that a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented **must** be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In the outstanding Office Action at pages 6-8, the Examiner provides arguments as to why the presently claimed invention requires undue experimentation based upon the scope of the claims, wherein the IRES is of plant origin. As discussed above, the inventive claims have been amended to be limited to IRESs from plant viruses with plus-sense single-stranded RNA genomes.

These genes can be easily identified, since plant viruses with plus-sense single-stranded RNA genome contain only a small number of genes. Thus, the presently claimed invention is sufficiently enabled to meet the requirements of 35 U.S.C. 112, first paragraph, and withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 20, 36, 38 and 41-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 6, 9 and 10 of U.S. Patent 6,376,745 (the '745 Patent). Applicants respectfully traverse the rejection.

Applicants respectfully submit that the inventive claims are not made obvious by the claims of the '745 Patent. However, in order to advance prosecution, Applicants enclose herewith a Terminal Disclaimer over the '745 Patent. As such, withdrawal of the rejection is respectfully requested.

In legal principle, the filing of a Terminal Disclaimer simply serves the statutory function of removing the rejection of obviousness-type double patenting, and does not raise the presumption on the merits of the rejection. It is improper to

view the simple expedient of "obviation" as an admission or acquiescence on the merits. *Ortho Pharmaceutical Corp. v. Smith*, 22 USPQ2d 1119, 1124 (Fed. Cir. 1992) citing *Quad Envtl. Technologies Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874, 20 USPQ2d 1392, 1394-95 (Fed. Cir. 1991).

Information Disclosure Statement

With the Application materials filed July 25, 2001 was included an IDS which listed the following reference:

> BIO/TECHNOLOGY, Volume 12, July 1994, Yoshikazu Sugimoto et al., page 694 - page 698

A copy of this reference was not filed as part of the IDS, since a copy of the reference can be found in the parent Application Serial No. 09/424,793. It is noted that the Examiner has not initialed next to the listing of this document on the PTO-1449 form attached to the January 10, 2003 Office Action.

Attached hereto is a copy of the reference and a PTO-1449 form listing the reference. The Examiner is requested to return a signed copy of the attached PTO-1449 form as evidence that this reference has been considered.

Conclusion

In view of the above amendments and comments, Applicants respectfully submit that the claims are in condition for allowance. A notice to such effect is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Garth M. Dahlen, (Reg. No. 43,575) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
Gerald M. Murphy, Jr., #28,977

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

GMM/MAA/GMD:bmp
4360-0102P

Attachment(s): 1) Terminal Disclaimer
2) BIO/TECHNOLOGY, 1994,
3) PTO-1449 form

(Rev. 02/12/2004)